

## Chapman Law Review

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Volume 11 | Issue 2

Article 5

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2008

# Transcript, Agency Preemption: Speak Softly, But Carry a Big Stick

2005 National Lawyer's Convention

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### Recommended Citation

2005 National Lawyer's Convention, *Transcript, Agency Preemption: Speak Softly, But Carry a Big Stick*, 11 CHAP. L. REV. 363 (2008).  
Available at: <http://digitalcommons.chapman.edu/chapman-law-review/vol11/iss2/5>

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**The Federalist Society for Law  
and Public Policy**

*presents*

**AGENCY PREEMPTION: SPEAK SOFTLY, BUT  
CARRY A BIG STICK?**

**2006 National Lawyer's Convention**

**November 18, 2006**

**PANELISTS:**

*Hon. Ronald A. Cass*, President, Cass & Associates, PC and Dean  
Emeritus, Boston University School of Law

*Professor Thomas W. Merrill*, Columbia University School of Law

*Professor Catherine M. Sharkey*, New York University School of Law

*Hon. Daniel E. Troy*, Sidley Austin and Former Chief Counsel, United  
States Food & Drug Administration

*Hon. Diarmuid F. O'Scannlain*, United States Circuit Judge, United States  
Court of Appeals for the Ninth Circuit (moderator)

**JUDGE O'SCANNLAIN:** It is a great pleasure for me to welcome you to our panel today, entitled "Agency Preemption: Speak Softly, but Carry a Big Stick?" As moderator, my task is twofold. First, I hope to frame the panel discussion by reference to preemption law generally, as well as recent events and developments in agency preemption.

Secondly, I hope to convince you of the enormous importance of this otherwise arcane topic, because, while it may sound esoteric, it goes to the heart of the constitutional order, in my view. As one scholar explained, the extent to which a federal statute displaces state law affects both the substantive legal rules under which we live and the distribution of authority between the states and the federal government.

Speaking generally, there are three types of preemption: express preemption, applied field preemption, and implied conflict preemption. This panel will focus on implied conflict preemption, which courts find either where it is impossible for a private party to comply with both state and federal requirements or where state law stands as an obstacle to the accomplishment and execution of the federal purposes and objectives of Congress. Given that we have a former official of the Food and Drug Administration on a panel today, I thought I would set the stage for today's panel debate by discussing a recent state court case dealing with agency preemption.

The case is *Levine v. Wyeth*,<sup>1</sup> by decision of the Vermont Supreme Court. The facts of the case are simple, yet sympathetic. Levine brought a tort action alleging negligence and failure to warn against the drug company, and was awarded \$6.8 million in damages by a jury. Her claim was that the warning accompanying the drug was insufficient to alert her and her doctors to the dangers of intravenous injection. The primary question on appeal was whether Levine's failure to warn claims were preempted by the FDA's approval of the particular label that accompanied the drug.

The Vermont Supreme Court essentially held that the FDA's approval of the drug label constituted a warning floor and not a ceiling. In other words, the court thought Wyeth could have, and should have, done more to warn Levine of the dangers associated with intravenous injection of Phenergan. In dissent, the Vermont Chief Justice argued that, by approving Phenergan for marketing and distribution, the FDA concluded that the drug, with its approved methods of administration, and label, was both safe and effective. He continued, "In finding defendant liable for failure to warn, a Vermont jury concluded that the same drug, with its FDA-approved methods of administration and as labeled, was unreasonably dangerous. These two conclusions are in direct conflict."<sup>2</sup> In the Chief Justice's view, the FDA's approval of the warning label constituted both a floor and a ceiling, and Levine's claims were preempted.

Such competing views raise important legal questions. In *Levine*, the drug company's position was bolstered by a statement of the FDA that cases rejecting preemption of failure to warn claims pose an obstacle to the Agency's enforcement of the labeling requirements. So, what sort of deference, if any, is due to an agency's statement about the preemptive scope of its regulations? Most broadly, in promulgating preemptive regulations and adopting statements regarding preemption, can and do agencies adequately protect the values of federalism? How should the traditional presumption against preemption operate in this realm? Finally, what is the best way to protect citizens like Ms. Levine?

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<sup>1</sup> No. 2004-384, 2006 WL 3041078 (Vt. Oct. 27, 2006).

<sup>2</sup> *Id.* at ¶ 45 (Reiber, C.J., dissenting).

The U.S. Supreme Court has the opportunity to enlighten us on the proper resolution of some of these difficult questions when it considers the case *Watters v. Wachovia Bank*<sup>3</sup> later this month. At issue in that case is a regulation promulgated by the Office of the Comptroller of the Currency, which states that unless otherwise provided by federal law or OCC regulation, state laws apply to national bank operating subsidiaries to the same extent that they apply to the parent national bank. The Sixth Circuit, following both the Second Circuit and my court, the Ninth Circuit, applying *Chevron* deference,<sup>4</sup> took the view that the Commissioner's regulations preempted Michigan banking laws in their entirety, as applied to the operating subsidiaries.<sup>5</sup> Perhaps one of the panelists will comment on why it is that the Supreme Court took *Watters*, given the fact that the three prominent cases all came out the same way.

In any event, to help us think about the many important issues and lead-up to *Watters* and beyond, the Federalist Society has gathered a distinguished group of scholars who will speak with us today. We will be hearing first from Daniel Troy, who is a partner in the Washington office of Sidley Austin, and immediately prior to that served as the Chief Counsel of the Food and Drug Administration, after being appointed to the position by President George W. Bush. In that role, Mr. Troy was an active player in the FDA's generally successful assertion of preemption in selected product liability cases. Mr. Troy is a graduate of Columbia Law School and served as a clerk for D.C. Circuit Judge Robert Bork from 1983 to 1984.

Next, we'll be hearing from Ronald Cass, who currently serves as the President of Cass & Associates. He previously served as the Dean of the Boston University School of Law from 1990 to 2004, and was a commissioner, and then later vice-chairman, of the U.S. International Trade Commission under Presidents Reagan and Bush I. Dean Cass is a graduate of the University of Virginia and of the University of Chicago Law Review, with honors. After graduation, he served as law clerk to the Honorable Collins Seitz, Chief Judge of the U.S. Court of Appeals for the Third Circuit.

We will then hear from Professor Catherine Sharkey, a newly-minted professor of law at Columbia Law School and currently a visiting professor at NYU Law School. Since joining the Columbia faculty, professor Sharkey has come to be recognized as a leading voice in the legal academy on both punitive damages and products liability preemption. Professor Sharkey is a graduate of Yale University, as well as Oxford, which she attended as a Rhodes Scholar. She is a graduate of Yale Law School and served as

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<sup>3</sup> *Watters v. Wachovia Bank, N.A.*, 127 S.Ct. 1559, 1573 (2007) (affirming the Sixth Circuit's holding that the Commissioner's regulations preempted Michigan banking laws).

<sup>4</sup> See *Chevron U.S.A. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843-44 (1984) (establishing the *Chevron* standard).

<sup>5</sup> *Wachovia Bank v. Watters*, 431 F.3d 556, 558 (6th Cir. 2005), *aff'd*, 127 S.Ct. at 1573.

law clerk for Judge Guido Calabrese of the Second Circuit and Justice David Souter of the Supreme Court.

Finally, we will hear from Professor Thomas Merrill, the Charles Keller Beekman Professor of Law, also at Columbia Law School. Professor Merrill recently filed an *amicus* brief on behalf of the Center for State Enforcement of Antitrust and Consumer Protection Laws in the *Watters* case that will be argued shortly. He is a graduate of Brunel College and also attended Oxford as a Rhodes Scholar. After graduation from the University of Chicago Law School, he served as law clerk to Judge David Bazelon of the U.S. Court of Appeals for the D.C. Circuit and to Justice Harry Blackman of the Supreme Court of the United States.

We will hear first from Mr. Troy.

**HON. MR. TROY:** Thank you, Judge for the introduction. It's a pleasure to be here.

Often those of us who are members of this Society and in favor of preemption in appropriate circumstances are accused of being hypocrites. Everybody says, "Well, it's the Federalist Society," confusing Federalists and federalism. I want to make clear that there is difference between the Federalist Society and being reflexively in favor of federalism. Madison was selected as the icon for our group not because of his much later states rights positions but because he was the father of the Constitution. Sometimes I think we should have selected both Madison and Hamilton, because it is, of course, the Federalist Papers after which the Society is named, and those Papers are in favor of a strong, albeit limited, central government.

It is important in the context of this conference, which is about limited government, to focus on the importance of preemption to limiting government. What do I mean? Well, in the case of food and drugs, if you have very strong federal regulation, but not preemption, you end up with perhaps 51 levels of government, 51 different systems that people need to navigate. Now, one can imagine a world with no federal regulation of drugs at all, with every state regulating. You might have competitive federalism, in that case, and you might not.

But when you have the system that we have, at least in the realm of drugs and medical products, you cannot begin to test a product on humans without getting the federal government to approve it in advance. You cannot market the product without the federal government approving it in advance. You cannot manufacture the product without the government approving it in advance. People hear the words "new drug application" and think, "Oh, college application." In fact, a new drug application normally has as much data, as many boxes of documents, as would literally fill this room. These applications are delivered to the Agency by the truckload. The Agency looks at that data and, for the purposes of this panel, compre-

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hensively determines what may and may not be said about the drug product through labeling. Labeling is not merely a floor, notwithstanding what the Vermont Supreme Court said.

What the FDA said in its most recent preemption preamble is that it is a floor and a ceiling. I want to illustrate that by talking about some specific cases, because the devil is in the details and, on the one hand, this stuff can be esoteric and arcane, but on the other, if you really look at the public health of the matter—and, I'd like to suggest, the common sense of the matter—I think the case for preemption becomes very powerful.

Let me talk about the case called *Dowhal*,<sup>6</sup> the California Supreme Court case. As many of you know, California has something called Proposition 65,<sup>7</sup> which requires warnings if there's any substance in a product that can either be carcinogenic or can cause harm in a pregnancy. The issue in the case involved nicotine replacement therapy products. These are products that somebody takes if they're trying to quit smoking. The FDA said, "We want the warning to say, 'Try to stop smoking without this product. This product can be useful, but talk to your doctor. Nicotine can have adverse impacts.'"

There was a lawsuit filed under Prop 65—which, to his credit, the California Attorney General did not join. The gravamen was that they wanted the nicotine replacement therapy product to say, "Nicotine can harm your baby." That was all. But the FDA rejected this warning in a series of letters and in more formal responses to citizens' petitions. It said, "We don't want that warning." That warning might cause a woman to misunderstand that, actually, nicotine replacement products are a good thing.

Well, the California Court of Appeals said, as the Vermont Supreme Court did, that it's always better to have more warnings, and the FDA got involved. One thing the federal career officials believe is that when they decide a matter, when they have, in the language of *Chevron*, directly spoken to the precise question at issue, they should get to win. So they thought in this case. Fortunately, we went to the California Supreme Court, and the California Supreme Court said, "Actually, more warnings are not always better."

Perhaps the most controversial case involved something called SSRIs (antidepressants). It is a tragic fact that people who are depressed tend to commit suicide. So, it's hard to tease out whether there's a connection between antidepressants and suicide. At the time these products were first approved, the question to the FDA Expert Advisory Committee was: Should there be a warning that these products might cause suicide? They said no because they didn't think there was data to support that. Secondarily, they thought it might dissuade people who were depressed from taking

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<sup>6</sup> *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P. 3d 1 (Cal. 2004).

<sup>7</sup> CAL. HEALTH & SAFETY CODE § 25249.5 (2007).

the drug.

There are many people concerned about antidepressants. So, for example, the Scientologists and Public Citizen came back to the FDA time and again asking the Agency to put this warning on, and the FDA kept saying, "We're sorry, but we don't think that's the right thing to do. It will over-warn. It's not just a floor; more warnings are not always better."

Well, a lawsuit was brought in the Tenth Circuit,<sup>8</sup> the thrust of which was that, in this case, Pfizer should have labeled its antidepressant product Zoloft to say, "This product can cause suicide." It was brought by someone who survived a relative who had taken the product and six days later committed suicide, tragically.<sup>9</sup> The district court said that more warnings are always better, the suit can go forward. Again, the FDA got involved and said, "Excuse me, we think that would have misbranded the product."

So, in talking about conflict preemption, it certainly begs the question, if the FDA thinks a product would be misbranded, how can state law requirements compel product labeling that would be technically misbranded and illegal under federal law? If that is not implied conflict preemption, I don't know what is.

The FDA has continued to intervene, but it's important to note that the Agency itself does not have litigating authority. The FDA intervenes through the HHS General Counsel's Office and the Justice Department.

It is the final backstop. This is, I think, one of the things that has caused this controversy and caused this panel. Instead of intervening with individual *amicus* briefs, the FDA issued this broad statement on preemption that basically said, "Our regulations are not just a floor, they're also a ceiling. More warnings are not always better. And when we make a decision we are not looking at the benefits and risks of a product in the context of an individual. We're making a societal decision. We understand that all drugs have risks. There are no drugs that are risk-free; people often forget this. And so, we understand when we put the product on the market that there will be some adverse events. That is an unhappy fact that comes from having therapeutic products. But we're making a broad risk-benefit calculation, and so that calculation must necessarily displace state suits that would have the effect of undercutting the FDA's definitive determination about the warning label."

And so, to close, this is part of what is sometimes called the "stealth tort reform" by the Bush administration. But it seems to me that if you're going to have a very powerful regulatory scheme, that there is naturally going to be some state regulation imposed through the product liability system that has to be set aside. Thank you.

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<sup>8</sup> *Miller v. Pfizer Inc. (Roerig Division)*, 196 F.Supp.2d 1095 (D.Kan. 2002).

<sup>9</sup> *Id.*

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**JUDGE O'SCANNLAIN:** Dean Cass.

**DEAN CASS:** Before I start, I have to say I had a phone conversation with my colleagues here, and I misunderstood the topic. I thought that they said talk softly and do shtick. So I'm going to begin with a brief anecdote.

This is actually a story my wife told me, involving a friend of hers who one day saw a funeral procession in the suburbs of Washington. It was a very unusual procession. In New Orleans, you're used to seeing that but not in Washington. It consisted of a hearse followed by a second hearse, followed by a woman dressed in black walking a dog, followed by a thousand women in single file.

My wife's friend went up to the woman walking the dog and said, "You know, I have to ask you. This is the most unusual funeral procession I've seen. Who's in the hearse?" The woman said, "It's my husband." "How did he die?" The woman pointed and said, "My dog attacked him. We were having an argument. The dog took it seriously, went berserk, and killed my husband." Her friend apologized and said, "Who's in the second hearse?" And the woman said, "It's my mother-in-law. She tried to intervene and the dog killed her too." Susie's friend thought for a minute and said, "Can I borrow your dog?" At which point, the woman said, "Get in line."

There are some ideas that seem like good ideas, and appeal to a lot of people. We're really not dealing with one idea here, but three: the idea of limited government, the question of the level of government appropriate to make a particular decision, and the question of which organ of government should make that decision. What's the right competence? Is it the courts? Is it the agencies? Is it the Legislature?

For me, the ultimate test is not, "does this get us a particular amount of government?" It's a combination of quantity and quality of government. If you look to the Framing, the concern wasn't just to limit government. After all, the Constitution expanded the national government in very significant ways over the Articles of Confederation. The goal was to preserve and protect liberty and security, which is done by having not the minimal government, but the right sort of government, delivered in the right way.

The Constitution gives the national government control over interstate commerce. It also has a provision decreeing that the national government should not tax or lay particular impediments to the trade coming out of any one state. It says to the states that they shouldn't lay taxes on the trade coming out of their states unless they're so directed by Congress; and the tax goes to the Treasury. What the Framers were quite clearly trying to do was to facilitate the free flow of goods among states. They were cognizant of the fact that if you don't give the national government the control over



the flow of goods within states, you will have a lot of impediments to trade, because states have an incentive to internalize benefits and externalize costs.

We see this all the time when you look at how state attorneys general deal with companies doing business in their state. They try to impose special burdens on the business that can bring benefits into their state; they try to localize regulation of what is a national or international enterprise; and they frequently do this using very ham-handed means, because if they were more transparent about what they were doing, it would be more difficult to get where they want to go.

The distinction Dan Troy drew between those who are Federalists, believing in a system with different levels of government, and those who believe that all decisions should be made by the state or local level, is a very important one. There are certain decisions that should be made at the state or local level because they deal with state and local problems. That is most congruent with protecting the liberty and the values of the people in those states or localities. When you deal with something that has national or international scope, giving states the right to speak to those issues can be counterproductive to liberty, security, and efficiency.

When we are trying to determine who ought to be making these decisions, we are often dealing with statutes that most of us might not like. We think the area of regulation may not be a good thing. We think the national government is excessively regulating. But to then say that the way to deal with this problem is to allow states to also regulate may impose additional duplicative and conflicting burdens on businesses. Those are the things we ought to disfavor and avoid whenever possible.

A lot of the cases we are dealing with here deal with the question: When an agency is regulating, what presumption should attach? Should the presumption be that an agency regulation ousts state regulation? Should we be relatively inclined or relatively disinclined to find conflicts? Historically, the rule has been that we are relatively disinclined to find conflicts.

The next level of argument is: Who ought to be making that determination? Here is where things have gotten more contentious. The courts have said that the agencies at the national level issuing regulations are given deference in interpreting the law because Congress intended, in creating this particular regulatory scheme, to authorize the agency to be the first place ambiguities are resolved. This is a matter of statutory interpretation. That interpretation logically extends to the interference or noninterference with the schemes of state and local governments.

Judge O'Scannlain asked, "Why, when all of the courts—the Ninth Circuit, the Second Circuit, the Sixth Circuit—came out the same way on this, did the Supreme Court take *cert*?" I think they were confused. They saw the six upside down and thought it was a nine. You know, the Su-

preme Court took cases from the Ninth Circuit to reverse your colleagues, not you. I also noticed that at the dinner the other night that there was a place for Judge O'Scannlain, but they did not put the usual "reserved" sign. They were afraid he would think it said "reversed".

**PROFESSOR SHARKEY:** Good afternoon. I want to talk about what I call an "agency reference" model—as distinct from an "agency deference" model—to be used in a court's determination of implied preemption, particularly in the products liability context.<sup>10</sup>

First, to set the stage, consider that the FDA and other agencies have recently enacted "preemption preambles"—statements included in preambles to final regulatory rules indicating the agency's belief that the federal regulatory standard preempts common law tort actions.<sup>11</sup> As Dan Troy has pointed out, the FDA included a statement of preemptive intent in its recent rule governing the format and content of prescription drug labels. NHTSA's (National Highway Traffic Safety Administration) preemption preamble appears in a recent notice of proposed rulemaking about roof safety standards. The Consumer Products Safety Commission, for the first time in its thirty-three-year history, proposed a preemption preamble in a 2006 regulation addressing flammability standards for mattresses. (The FDA and NHTSA had done so previously.)<sup>12</sup> Given the flurry of recent federal agency activity here in Washington, D.C., this topic has real currency.

The agency reference model is a middle-course approach to guide courts in making implied preemption determinations. Where Congress is clear about its intent to preempt or displace state law, its intent would govern. It turns out, however, that when Congress enacts piecemeal legislation concerning specific products, such as the Motor Vehicle Safety Act or the Federal Boat Safety Act, Congress has been anything but clear. Typically, these product statutes include very broad preemption clauses that expressly preempt any conflicting state requirement. Congress usually says that state "requirements" or "standards" are preempted, using broad language that has been read to include common law state tort actions. These broad preemption clauses are coupled with very broad savings clauses that purport to leave common law actions intact. In these instances, Congress seems to be saying everything. In other instances, such as the Food Drug and Cosmetic Act, it is all but silent. In the provisions that deal with medical products, there is a preemption clause, but in the provisions dealing with drugs, there is not. As Congress does not expressly answer the

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<sup>10</sup> For an elaboration of this framework, see Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. \_ (forthcoming 2008).

<sup>11</sup> See Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227 (2007).

<sup>12</sup> 21 C.F.R. § 201 (2006); 49 C.F.R. § 571 (2005).

preemption questions that products liability cases implicate, there is ample room for other decision-makers—namely, courts and agencies—to step in.

Congress's failure to weigh in on the issue of preemption of common law actions, which cannot realistically be ascribed to inadvertent omission, is puzzling. For example, associated with the Federal Insecticide, Fungicide and Rodenticide Act, at issue in the recent Supreme Court case of *Bates v. Dow Agrosciences, LLC*,<sup>13</sup> there are over a thousand pages of legislative history and yet not a word about the fate of state common law tort actions. But when this Act was amended in 1972, such actions were quite common. The interesting question is an institutional one: Does Congress punt the preemption determination to courts or to agencies? How should this interplay work? The agency reference model that I advocate would leave the decision-making power in courts, but not allow them either to give mandatory deference to the agency position or to ignore the agency's position.

Contrast the present situation where courts are taking extreme positions when faced with the issue of whether the FDCA and regulations promulgated thereunder by the FDA preempt common law failure to warn claims. In his remarks today, Judge O'Scannlain mentioned the *Levine v. Wyeth*<sup>14</sup> case, which exemplifies one extreme pole, where courts say that there is a "presumption against preemption" and that the purpose of the FDCA is to protect health and safety, so how could any state tort action ever be preempted? The idea that more regulation is always better seems clearly wrong in the context of drugs or any product situation where the determination rests upon risk-risk tradeoffs. If you add warnings, you're not just warning consumers of certain risks, you are inevitably creating alternative risks insofar as individuals, or their physicians, are scared off from these drugs. That is one extreme.

At the other extreme lie courts that defer unconditionally to the FDA's "misbranding" argument in favor of preemption of common law claims: that a manufacturer can never unilaterally strengthen or alter a label warning, lest it risk being prosecuted by the FDA for misbranding the drug. The upshot is that the FDA's pre-market new drug approval process would grant the drug manufacturers immunity from state common law tort actions (most often failure to warn claims). And this safe harbor would protect drug manufacturers even in situations where new risks (of which the manufacturer was aware) come to light in the post-approval period.

But between these extreme positions lies a middle-course approach, whereby courts would be able to look specifically at the risk-risk determination by the Agency—not just at the time of approval, but during the post-approval period as well. Most of these cases deal with situations where

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<sup>13</sup> 544 U.S. 431 (2005).

<sup>14</sup> No. 2004-384, 2006 WL 3041078 (Vt. Oct. 27, 2006).

new risks allegedly came to light in the post-approval process. The manufacturer then has an opportunity to go back to the FDA.

In *Levine*, the manufacturer went back to the FDA (during the post-approval period) to try to strengthen a warning for a different variety of the drug and was told to “[r]etain verbiage in current label.”<sup>15</sup> The court nonetheless held—erroneously, in my view—that a state law failure to warn claim was not impliedly preempted by the FDA’s regulatory action pursuant to the FDCA.

*Perry v. Novartis*<sup>16</sup> embodies the middle-course approach that I am advocating here. The federal district court rejected the two extreme positions: at one pole, that the FDA’s preemption preamble should be rejected altogether, and at the other pole, that the preamble should be accorded mandatory *Chevron* deference. Instead, the court decided that the FDA’s views embodied in the preamble should receive *Skidmore*, or “power to persuade,” deference.<sup>17</sup> I think that the *Perry* court staked out the correct approach.

Moreover, this middle-course position comports with the U.S. Supreme Court’s jurisprudence. I unearthed an interesting positive empirical finding when doing a study of products liability preemption. If you look at the U.S. Supreme Court’s product liability preemption cases, which span from *Cipollone*<sup>18</sup> to *Bates*,<sup>19</sup> in every case (save *Bates*), the Court’s ultimate decision, whether pro-preemption or anti-preemption, aligns with the position urged by the relevant agency. Thus, the FDA had argued in favor of preemption in *Buckman*,<sup>20</sup> and the Court went that way; it argued against preemption in *Medtronic*,<sup>21</sup> and the Court went that way. NHTSA argued in favor of preemption in *Geier*<sup>22</sup> and against preemption in *Freightliner*,<sup>23</sup> and the Court followed suit. The Court’s anti-preemption holding in *Sprietsma*<sup>24</sup> likewise follows the agency’s position. The Coast Guard, having done a risk-risk analysis, came to the conclusion that no uniform propeller guard design was suitable, given the variety of recreational boats and motors in existence; and thus, a state law design defect claim in no way interfered with any federal policy reflected in its decision not to regulate.

The Supreme Court has been very cryptic. It has never said, “We are applying *Chevron* (or *Skidmore*) deference here.” Most often in dissent, Justices try to force the issue by saying, “Look, the Justices in the majority

<sup>15</sup> *Id.* at ¶21.

<sup>16</sup> *Perry v. Novartis Pharm. Corp.*, 456 F.Supp.2d 678 (E.D.Pa. 2006).

<sup>17</sup> *Id.* at 683.

<sup>18</sup> *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

<sup>19</sup> *Bates v. Dow Agrosiences LLC*, 544 U.S. 431 (2005).

<sup>20</sup> *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001).

<sup>21</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

<sup>22</sup> *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861 (2000).

<sup>23</sup> *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995).

<sup>24</sup> *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002).

are giving deference by saying things like 'We give significant weight to the Agency's determination,' but they never come out and say they are according *Chevron* deference." If you look carefully at what the majorities in those cases do, though, I think they apply something that looks like *Skidmore* deference, and in general provide a model for courts to follow.

One last observation: if you look at the dozen or so cases that post-date the issuance of the FDA's preemption preamble, some have been decided by federal courts, some by state courts. The state courts have, over the past quarter century, consistently rebuffed the regulatory compliance defense to state common law tort actions; it is hardly surprising, then, to find that state courts, on the whole, seem predisposed to resist the idea of federal preemption of state law, which after all, is essentially an even more forceful immunity-conferring mechanism. The federal courts seem more likely to listen to what the FDA says, and the FDA is much more likely to intervene in federal cases, either on its own or when the Court asks for its views.<sup>25</sup> That will be a very interesting dynamic to observe over time.

Thank you.

**JUDGE O'SCANNLAIN:** Our final panelist will be Professor Merrill.

**PROFESSOR MERRILL:** Thank you very much. I notice that the room is a little crowded in the back, so in the effort to clear things out, let me announce in advance that I'm going to be talking about administrative law doctrine for the next eight minutes. In case you want leave quickly, now is your chance to do that.

I'm going to approach this from the perspective of administrative law rather than tort law or ordinary preemption law. I think when you approach it from a perspective of administrative law, you discover that the range of disagreement here is actually quite narrow; that a number of propositions which you might think would be contestable in fact have been resolved, more or less, by express holdings of the Supreme Court or by settled propositions (or at least what I regard as several propositions, of administrative law). So, let me mention three things that I, at least, regard as settled propositions, which have the effect, I think, of compressing the area of disagreement down to a fairly small point.

First, it's well established that agency legislative regulations have preemptive effects. If an agency has been delegated power to act with the force of law, to issue legislative regulations, where those legislative regulations are deemed inconsistent with state law—by the court, at least—

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<sup>25</sup> See Catherine M. Sharkey, *Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts*, 15 BROOKLYN J.L. & POL'Y 1013 (2007).

there's no question that the federal regulation trumps or preempts state law. This was held back in 1961 in *United States v. Shimer*<sup>26</sup> and reaffirmed in the *de la Cuesta*<sup>27</sup> case in 1982. The issue is off the table.

Second, if Congress expressly delegates authority to an agency to issue preemptive regulations—not just legislative regulations, but regulations that say, “We deem state law in Area X to be preempted”—that is permissible as well. There are a number of examples in federal law where Congress has given express preemptive authority to agencies, whose exercise of that authority has been upheld by courts. The Supreme Court's authority at this point is a little sketchier. If I had my way, the Court would insist a bit more on the need for express delegated authority to preempt, rather than finding it in some kind of clearly implied fashion. There's a case called *New York v. FCC*<sup>28</sup> from 1988, in which the Supreme Court found express authority to issue preemptive regulations based on congressional ratification of prior practice by the agency, which I think is pushing it a little far. But the basic proposition that Congress can expressly delegate preemptive authority to an agency, I think, is off the table as well.

Thirdly, an agency's statement of its opinion about the preemptive effect of either the federal statutory scheme or a combination of the federal statutes and federal regulations is not entitled to *Chevron* deference. The reason for this follows from recently established principles about when *Chevron* does and does not apply. The infamous *Mead* case that Ron tried to make me promise not to mention, holds—, well, who knows exactly what it holds?—I think it holds that agencies are entitled to *Chevron* deference only if they act with the force of law; meaning that they're issuing something like a legislative regulation which is within their delegated jurisdiction. If they issue an interpretation of rule or some kind of opinion letter, that's not entitled to *Chevron* deference.

Now, with respect to these preambles, the issue is a little bit trickier. I take it that a statement in a preamble about the preemptive effect of a federal regulation being adopted pursuant to whatever perambulatory statement does not itself have the force of law. Administrative lawyers distinguish all the time between what's called the Statement of Basis and Purpose required by Section 553 of the APA and the regulation itself. The regulation itself is a thing that goes into the Code of Federal Regulations. That's what has the force of law. The statement in the preamble is the explanation for the regulation. It does not of its own effect have the force of law.

If an agency has to interpret federal statutory authority in order to reach a particular legislative regulation, and the explanation for its statutory

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<sup>26</sup> U.S. v. Shimer, 367 U.S. 374 (1961).

<sup>27</sup> Fidelity Federal Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141 (1982).

<sup>28</sup> City of New York v. F.C.C., 486 U.S. 57 (1988).

authority is in the preamble, it is entitled to *Chevron* deference, because the explanation is the condition precedent for the regulation itself. But if you have something like a regulation dealing with drug labeling and the FDA says in the preamble, "By the way, it's our opinion that any state court action inconsistent with this labeling would be preempted," that's just a statement of agency opinion; it's not a necessary condition of finding authority on the part of the agency to issue that regulation. It would not be entitled to *Chevron* deference.

So, I think those propositions are pretty much settled.

What is not settled is the issue presented by the *Watters* case, which is going to be argued on November 29. The issue is: What happens if an agency that has legislative rulemaking authority—but has not been given express authority to issue preemptive regulations—uses its general rule-making authority to issue what purports to be a legislative regulation, which regulation then states the agency's determination that state law in a particular area is preempted? Is that sort of legislative regulation pursuant to a general delegation of authority rather than to an authority to preempt also entitled to *Chevron* deference, or to some lesser degree of deference, presumably *Skidmore*?

In answering this question, I think we have to revert to more general principles and not simple case law and settled principles of administrative law. Several propositions are relevant here in sorting things out. First of all, I do not agree with Ron's statement that determinations of preemption are simply a species of statutory interpretation.

In preemption cases, there are three determinations to be made, not just one. The first determination is that somebody, be it a court or an agency, has to decide what the federal law means or requires. That's an exercise of straightforward interpretation. Then, the decision-maker, be it a court or agency, has to decide what the state law means or requires. That's another exercise in interpretation. The third step is critically different; that is, the decision-maker has to decide how much tension there is between the federal and the state law, if any; and, given the degree of tension, whether it's necessary to displace or nullify state law in order to effectuate the general purposes of the federal statutory regime.

Now, in some instances, that third step is not necessary. You've got an express preemption clause which is squarely on point; that would not be a contested case. In all other cases, if there's a dispute about the scope of an express preemption clause, something about obstacle or frustration of purpose preemption or field preemption—even, in most cases, of conflict preemption where there's not a square X or Y type of conflict—somebody has to decide whether a displacement of state law is necessary.

So, the question is really one of institutional choice, as several of the other speakers mentioned. Who is going to make this determination of displacement? I think an argument can be made that the agencies ought to be

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given significant say-so in this exercise. The agencies, after all, have great expertise about the nature of the statutory scheme. They probably have a unique understanding about how state law is or is not going to interfere with the way the federal statutory scheme is carried out. But let me give you some quick reasons why I think strong *Chevron* deference probably is not the way to go in making this displacement determination. I'll just mention these quickly.

First of all, and Cathy mentioned this briefly, preemption is an issue that comes up in state court almost as often as it comes up in federal court. I have trouble imagining exactly how the U.S. Supreme Court is going to enforce a duty upon state courts to give *Chevron* deference to federal administrative agencies on the question of preemption. The Supreme Court just does not have the institutional capacity, I think, to change state court behavior in that radical direction. Something like a *Skidmore* doctrine, which allows agencies to submit their views in various ways and instructs courts to give them effect insofar as they are persuasive, would, I think, be something more reasonably workable in the state court system.

Secondly, I think there are systemic considerations here. Most of our panelists are interested in explaining how Madison was really in favor of a powerful federal government, but there are systemic interests here in terms of maintaining a balance between the federal government and the states; that is, not having the federal regulatory juggernaut completely take over our system. I'm concerned that if each federal agency which has a little individual regulatory slice of the world is given *Chevron* deference for its determinations, we're going to see a lot more displacement of state law. There will be a tendency for each agency individual to push the limits of federal law in isolation. We need some kind of judicial counterweight to that. I think the federal judiciary, the Supreme Court in particular, which has a broad-brush picture about the need for state and federal balance in the system, is a better institution to maintain that balance than are individual agencies.

Lastly, and I'll close with this point, the question of whether agencies can preempt or be given strong *Chevron* deference for preempting state law is another one of these issues that implicate the scope of an agency's authority. All sorts of scope issues come up about whether agencies can regulate with the force of law or not. But there are reasons to be concerned about giving that issue to states to decide under a strong deference doctrine like *Chevron*. Agencies would have a tendency to view state regulators as rivals, to see state courts as rivals, and try to expand their authority. We need federal courts to discipline the boundaries of agency action. *Skidmore* is better suited to doing that than *Chevron*.

Thank you.

**JUDGE O'SCANNLAIN:** Well, I want to thank the panelists for lay-



ing out all of the considerations very, very effectively. Before we take questions from the floor, I thought I would offer the opportunity for each of the panelists to comment on anything any of the others have said. And since Mr. Troy went first, he'll have the first crack.

**HON. MR. TROY:** Thank you. I think Tom expected me to start throwing things at them on the question of *Chevron* versus *Skidmore* deference. I think they are very strong arguments, which I understand, for according *Skidmore* deference, but I want to make couple of points. First of all, the preamble—there's preemption whether or not the Agency came out with the preamble, and the Agency was asserting that there was preemption before that. The key point is, what are the decisions that the agency is making, and what kind of a position does it put the company in? So that's point one.

Point two: The FDA was very clear that you do need to come post-approval and adhere to the very stringent regulations which require you to notify the Agency of additional decisions, of additional information, and a company's obligations do not end once the product is approved. An FDA scrutiny of a product does not end once the product is approved. This is a misconception. Companies are required to collect adverse event data and to feed it back to the Agency under very stringent time frames. The Agency continues to monitor that data.

But this *Levine* case, which I am not involved with, let me confess—although I do generally represent, at this point, many clients in connection with these issues—but in the *Levine* case, I want to spend a moment on it to show what an existential threat it is to FDA, what an untenable position it puts the company in, and how bad it is for the public health. In this *Levine* case, basically FDA look at the data. The company came and said we want to put this additional warning. And FDA said we don't think it's warranted. We think the current route of administration, notwithstanding that it has some very serious side effects—in this case, the women, tragically, who is very popular local musician, lost her arm—but we believe this is the proper route of administration, looking at all of the data.

And so, the company actually not only gave in all the relevant data, but the company actually proposed an additional warning. FDA wrote back formally, “retain current verbiage”. If a state court can come along and say who cares what the FDA says, Company, you needed to do something else, what does that say, A, about the FDA's ability to decide what is and is not on a drug label; B, what is the company supposed to do?

I'm not saying that any time a company changes its warning before FDA has officially blessed it, there's misbranding. But there are circumstances where FDA has said, you know what, you can't just slap any warning that you want for sort of just defensive labeling purposes. The problem with that, and this gets into the public health point, is the labels have be-

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come—let's be clear. When we're talking about FDA labeling, we're talking about those little things that are folded that are in, you know, tiny, tiny, tiny font that fill pages and pages and pages and pages that basically nobody can read—which we all read slavishly before we take each pill—those are actually intended for the physician, but even the physicians, they have become so prolix that FDA found that they were being written too much as defensive legal documents rather than as risk communication documents to doctors. And so the context in which FDA put out this preemption statement was a context in which it was overhauling that labeling, that physician label, and it was saying we're going to try to make this simpler. And what happened in the sort of run-up to it was the company said that's a great idea. Less is more. You know, doctors and health care practitioners will be able to understand more if the thing is simpler. But if you make us take out warnings, we're going to get killed in product liability litigation and failure to warn litigation.

So the FDA said, well, we think it's a better thing for the public health, that better decisions will be made, if you have, for example, the summary provision that they called highlights, and we're going to say that if we tell you that you have to take something out or exclude something from highlights so that the public health goal can be achieved of a clear, simple message to doctors. If we're telling you to do that, you shouldn't be held liable by state courts for failure to warn. And that was the context in which FDA ultimately issued this.

Now, whether it gets strong *Chevron* deference or whether he gets *Skidmore* deference, I think it's sufficiently persuasive that it doesn't really need strong *Chevron* deference to prevail. Obviously, some state courts have disagreed, and this is an issue that is going to be—there's going to be further judicial resolution of it. But the public health of the matter is such that we really do have and need to have one agency that determines what doctors are and should be told about a product, as long as that agency is being given the relevant information as quickly as possible, and as appropriate.

**JUDGE O'SCANNLAIN:** Any rejoinder from the Academy?

**PROFESSOR SHARKEY:** Two quick points. The first one is, listening to Mr. Troy, it seems like he might adopt my middle-course approach, which of course would get me very excited.

**HON. MR. TROY:** I didn't realize I had that power.

**PROFESSOR SHARKEY:** *Levine* is a case that we would both see

as being wrongly decided case. There's strong evidence that, in that instance, the FDA actually rejected increasing the strength of the label. But would you adopt more broadly my middle course position?

*Perry v. Novartis*,<sup>29</sup> which you have not talked about, is a case in which the court finds no preemption and looks to the fact that the FDA didn't make a specific determination regarding the relevant risk one way or the other. A more extreme position—either the FDA's misbranding argument or *Chevron* deference to the pro-preemption position embodied in the preamble—would have led the court to the opposite result. In fact, the court held that there was no preemption specifically because the FDA was looking at a bunch of inconclusive evidence and wasn't able to make a definitive determination to regulate or not. *Perry* is thus a less clear-cut case than *Levine*, given the scientific uncertainty surrounding the risk and the FDA's apprehension at weighing in prematurely.

The contested ground is going to be in these contexts, where the relevant agency doesn't regulate, and you need to ask "Why not?" In *Sprietsma*,<sup>30</sup> for example, the Coast Guard didn't pass a uniform federal regulatory standard for boat safety, and it came up with some reasons like, given that the boats are designed in various particular ways to suit local conditions, it was not possible to come up with one uniform standard. What the Coast Guard, in not regulating, did not say that it wanted to leave the determination to the market or that it specifically wanted to displace state law. In such contestable cases where the FDA has not made a specific determination, I wonder whether Mr. Troy would sign on to my middle ground position.

The second quick point I'd like to make focuses on the disclosure of information to the FDA. I agree with what Mr. Troy said with respect to the FDA attempts to tell the drug manufacturer that they have all sorts of obligations to come back with new information. A new report just came out studying the FDA, which shows how the FDA can enforce the promises that they ask of drug manufacturers. In a similar vein, I think our system should think about crafting rules to be information-forcing. My middle-course approach places a burden on the manufacturers to come back to the FDA with evidence of newly discovered risks during the post-approval period. Fraud perpetrated on the FDA is another matter.<sup>31</sup> The FDA's preamble contains a "fraud caveat," suggesting that FDA-approval based preemption is conditional upon the manufacturer's not having withheld information from the FDA. But how will this disclosure of information be policed? The problem is that the Supreme Court has said, in *Buckman*, that fraud on the FDA claims are preempted. Unless the FDA polices not only

<sup>29</sup> *Perry v. Novartis Pharm. Corp.*, 456 F.Supp.2d 678 (E.D.Pa. 2006).

<sup>30</sup> *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002).

<sup>31</sup> See Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 NW. U.L. REV. \_\_ (forthcoming 2008).

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fraud but incomplete information disclosure as well, a kind of regulatory void is created.

**HON. MR. TROY:** A company is obligated to reveal to the Agency every adverse event it finds out about, and that is enforceable. If you don't do so, there are, can be, and have been—for example, *Guidant*—criminal penalties associated with that. The thing that people said that FDA cannot enforce is commitments post-marketing to do certain clinical trials, okay? But companies have an ongoing legal obligation to monitor and report to the Agency every adverse drug experience that they find out about, and they have obligations to do what they can to try and find out that information. It's just specific studies that the Agency currently cannot compel people to do post approval.

**JUDGE O'SCANNLAIN:** Dean Cass.

**DEAN CASS:** Thank you. Some of you may have noticed it's very difficult to open the doors in the back. That's for a reason. We knew we'd be talking about the difference between *Skidmore* and *Chevron* deference.

**JUDGE O'SCANNLAIN:** It came to that, didn't it?

**DEAN CASS:** After 30 years of law teaching I recognize that glazed expression, and I want to offer a word of explanation before I disagree with my colleagues. There are some concepts that are so complicated that only administrative law professors could embrace them.

For those of you who are not familiar with the jargon, *Chevron* deference is what I give to my wife. I know we're going to wind up doing what she says, so we start out with the presumption that that's what we're going to do.

*Skidmore* deference is what she gives to me.

**HON. MR. TROY:** If you get *Skidmore* deference, you are a lucky man.

**DEAN CASS:** There are many reasons I am a lucky man.

**PROFESSOR MERRILL:** Whatever happened to no deference, Ron?

**DEAN CASS:** The nice thing about *Skidmore* deference if it means that we do what I say when she's persuaded that she wants to do it anyway. And that's why the notion of *Skidmore* deference is a wonderful concept for courts, which means that they do what the agency says when they would've done it without the agency doing it anyway.

I think that we are better off having very simple concepts here. When Tom says that the Supreme Court can't police all the state courts and can't make sure they give *Chevron* deference, that doesn't strike me as a reason for telling them to give agencies no difference in all, which is essentially what the alternative is that Tom has moved to. I think that we have a world in which either we can give deference of some undefined magnitude or really not give deference at all. Courts talk about *Skidmore* deference when they aren't really deferring to the agency.

I think that we also are in a world where, when agency is making decisions, it is making decisions trying to do the sort of risk-risk analysis you're talking about. I think agencies, as bad as there are times at doing this, are far better suited to that than courts are. I have the utmost respect for judges, but I know many of them. And the last thing you want to see is having judges make this sort of complex risk-risk analysis. It's like I know they're going *Dancing with the Stars* now—watching the ordinary football player dance is not a pretty thing.

**JUDGE O'SCANNLAIN:** Before calling on Professor Merrill, I would like to invite any of those among you who would like to ask questions to come up to the microphone, and we will recognize you in the order in which you appear.

Professor Merrill.

**PROFESSOR MERRILL:** Well, I don't think *Skidmore* deference is no deference at all. I think that's much too cynical a view both about courts and about agencies.

Bill Eskridge has a study that he is finishing up now in which he looks at every Supreme Court decision involving a federal agency going back to 1950 or something like that.<sup>32</sup> And it's an interesting study. He shows that federal agencies do very well; they win about 70 to 75 percent of the time. And there doesn't seem to be much of a correlation between the *Chevron*, *Skidmore*, or cases where there is no express tentative review at all. So to that extent, I guess that does tend to reinforce the idea that these standards

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<sup>32</sup> William N. Eskridge, Jr. & Lauren Baer, *The Supreme Court's Deference Continuum, An Empirical Analysis* (*Chevron to Hamdan*), \_\_ GEORGETOWN L.J. \_\_ (forthcoming 2008).

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of review don't really matter that much.

But that's a study about the Supreme Court, and the Supreme Court I think maybe a little different from the lower courts, where I have a feeling that *Chevron* deference really does make a difference. When federal courts think that *Chevron* applies, they shift into a different mode of thinking about agency decisions than they might otherwise think about them.

The other interesting observation that's come out recently, is Nina Mendelson has a study about this issue in the *Michigan Law Review*,<sup>33</sup> and she looked at all of the agency decisions that were rendered under the executive order requiring federalism impact statements. She reports, quite strikingly, that when agencies do talk about preemption, the analysis is not very illuminating. The usually just try to follow judicial preemption doctrine and predict how a court would decide the preemption issue, rather than actually discussing underlying substantive issues about how much state law is going to interfere with federal law and how important it is to have a uniform federal scheme in a particular area.

One of my thoughts about the desirability of *Skidmore* is that *Skidmore* really would force the agencies to try to persuade courts about whether preemption is acceptable or not acceptable, and so it might, in a helpful sort of way, cause them to give more thoughtful consideration to the underlying policy variables, which is after all what we're really looking to them for illumination about. And if they just announce that they think it's preempted or not preempted and they are entitled to *Chevron* deference for that, we're really not going to get some of the benefits from agency decision making that we could potentially get under a different standard of review.

**JUDGE O'SCANNLAIN:** Thank you very much.

Now, the floor is open for questions. Please give us your name and your hometown.

**AUDIENCE PARTICIPANT:** Thank you, sir. My name is Brad Tupe. I'm from Pittsburgh, Pennsylvania. In any of these product liability trials, in the courtroom you have the plaintiff telling the story of the injury—the adverse reaction, the chemical exposure or whatever the case may be—you have an expert witness that testifies that if only the manufacturer had added a certain line to the warning, this never would have occurred, which is usually fallacious. And then you have a jury that hears evidence over the course of a few days, maybe a day, maybe a week, maybe longer, deliberates an hour or two; a jury made up of people, some of

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33 Nina A. Mendelson, *Chevron and Preemption*, 102 MICH. L. REV. 737 (2004).

whom have college educations and some of whom don't, who then determine, in the case we're discussing, that the plaintiff should receive a multimillion dollar award.

Contrast that with the negotiation, the adversarial negotiation that occurs between a manufacturer and either your agency, Mr. Troy, or the EPA in the case of a FIFRA pesticide, that takes years, millions of dollars, truckloads of documents, and you're going to have a situation where a jury hearing evidence for just a couple of days can substitute a judgment for this adversarial agency process. It doesn't make any sense.

What's really going on, I submit, and I'd be interested in your response, is that the courts are saying that the manufacturers are insurers, and that every injury must have a remedy, and that's never been our law.

**JUDGE O'SCANNLAIN:** I think there's a question in there somewhere. Responses?

**HON. MR. TROY:** Well, you make a very good point. I'm not sure that everybody in the industry would necessarily characterize their relationship with FDA as adversarial. There is, you know, a lot of cooperation and collaboration because, frankly, companies have an interest in an appropriate label that does adequately address the risks of the product, in part because it protects them in product liability and partly because they want to—you know, they have reputational interests in a lot of contexts, especially vis-à-vis position physicians. And it will not do if, you know, they are underestimating or understating what the risks are. And then, physicians can end up with, you know, bad outcomes and themselves getting sued in medical malpractice. And let's—you know, even though we're all lawyers, let's be clear that it's not the law that motivates everybody in the healthcare system. There are actually some people who want to make people better and want to do the right thing.

But you're right. You're right, and one of the ideas that people have floated in the drug contexts is, should there be some kind of better way? Should there be some kind of alternative compensation system, since we know to a moral certainty when a product is approved that there are going to be a certain number of people who are going to be harmed by it? Let's take statins, those cholesterol-lowering drugs which are literally miracles of modern technology, and the most important thing that any of you can do is go and check your cholesterol and probably—this is what Bob Temple, the dean of the drug approval process, always says—the most popular public health development in the last 15 years has been development of statins.

We know there are going to be a certain number of people who get a terrible condition called rhabdomyolysis. Is it worth it societally for those 50 people who are going to get rhabdomyolysis to have the incredibly posi-

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tive public health benefits associated with statins? Of course it is. Should something be done for those 50 people? You know, there's a pretty good case that there should be. Should it be handled through our tort system, which is essentially a lottery? I would argue the answer to that is not.

**JUDGE O'SCANNLAIN:** Dean Cass.

**DEAN CASS:** Well actually, having spent 15 years as a dean, I'm at my best turning the mic on and off for my colleague here.

I think it's very important to recognize that there will be cases when it is appropriate to have the issue handled through the tort system. My disagreement, I think, with Tom and Catherine is over where the presumption should lie on who should make that decision. And I think that while the agencies do have incentives to overreach, the complex decision, the amount of difficulty in trying to figure out what should be opened up to other mechanisms and what should not, is so difficult, and it is so likely to be gotten wrong because the competence of the decision maker in a state court litigation is so much less sophisticated at making this decision, so much less geared to making this decision, even if they had every incentive to do that, I think that the risk of doing it that way is greater. So my presumption would lie with the ability of the agency to say don't do that.

**PROFESSOR SHARKEY:** It is important to frame the debate as the balance and interplay between state common law tort and regulation.

I want to sound two notes of caution for people who are in favor of broad preemption of state tort law. First, the argument in favor of preemption can become overdetermined. Take, for example, the position of Richard Epstein, a colleague at University of Chicago. Richard believes that product liability cases should be handled in contract, not tort law. Having failed to convince the academic community or the prevailing court systems of that view, he then moved to the view that there should be a very strong regulatory compliance defense. Regulatory compliance as an absolute defense was an abject failure in terms of taking hold across state jurisdictions. It turns out there are very few state outliers. Michigan is the only state that has a regulatory compliance statutory defense that's almost airtight. Having failed there, Epstein moves to a position in favor of preemption across the board here. But even he will say this is therefore an overdetermined view. It doesn't actually rest on the nuances of Supreme Court jurisprudence on preemption principles. To my mind, the intersection between preemption principles and the tort law regulatory balance are actually important issues to think about.

The second note of caution is to recognize that all federal agencies should not be treated as equals. It is often said that the United States, as



compared to Europe or other countries, regulates products mostly *ex post* via litigation. Of all the federal agencies, the FDA engages in the most stringent *ex ante* regulation. The stringency of *ex ante* regulation might directly affect our views of agency preemption. Would we, for example, want to defer to agency preemption when the relevant agency is the Consumer Product Safety Commission which regulates without undertaking the kind of comprehensive review conducted by the FDA? Would our views on preemption change depending upon the particular federal scheme, and corresponding statutory authorization for the relevant agency? For these reasons, I think it's important not to let a view that juries can't decide issues swamp what actually could lead to a principled argument for preemption in a particular context.

**JUDGE O'SCANNLAIN:** Next question from the floor.

**AUDIENCE PARTICIPANT:** Richard Samp from Arlington, Virginia. Very often the Supreme Court, in its preemption cases, says, well, we start with a strong presumption against preemption because, after all, the Congress is known to be so respectful of the use of states that they would never want to unknowingly preempt some sort of state law. And while sometimes I think that's just to make way argument that's put into the cases, I think at least Justice Ginsburg believes that because she were repeatedly say, well, even when there's evidence that Congress intended to preempt affirmative state regulation, I think it would be just so outlandish that they would ever want to preempt a common law tort suit. But I'm just never going to agree that there is such preemption, unless Congress says that explicitly.

Certainly, as you can tell from the gist of my question, I think this whole idea that Congress really starts with this presumption against preemption just has no empirical basis. And it seems to me that if a court looks very carefully at all the evidence and it says, well, it's a close question, but we think that at the end of the day the evidence is slightly in favor of preemption, it would make no sense to say, but nonetheless because there's a presumption, we're going to shift the balance and go against preemption.

I'm wondering if there is anybody on this panel who would support the idea that there also be a presumption against preemption?

**JUDGE O'SCANNLAIN:** Professor Merrill.

**PROFESSOR MERRILL:** Not me, but—

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**JUDGE O'SCANNLAIN:** But you have the floor. It's okay.

**PROFESSOR MERRILL:** I think the problem with the presumption against preemption is it's just too overly broad. I mean, you could either have a presumption in favor of the states in every case or a presumption in favor of the federal government in every case. Either one of those rules would be overly broad.

The presumption against preemption fails to account for the fact that we have a federal government of enumerated powers. And so, in some areas, the regulation of interstate commerce, for example, why would you have a presumption against preemption? Because that's presumptively an area where the federal government has exclusive, or at least plenary, authority to regulate, and the dormant Commerce Clause stands as testament to the fact that there is in fact a presumption in favor of federal regulation in that area.

The more interesting aspect of your question I think is this question about to what extent the states are represented in Congress. This is an argument that Herbert Wechsler pioneered back in the 1950s, and it continues to have adherents, and it is offered as a justification for federal courts not overriding state prerogatives in different areas.

One interesting thing I'm sort of struggling with right now is to what extent does that sort of perspective apply to administrative agencies to either an equal, lesser, or greater extent than to Congress itself? Again, I think the answer is probably it all depends on what agency you're talking about. We have a lot of administrative agencies, and EPA is the one I'm most familiar with, where most of the regulating under the federal statutes is done by state administrators, and so federal EPA is constantly interacting with state regulators on a daily basis and is very familiar with state perspective on problems. In that sort of context, you might say that the agency really is a very effective representative of state interests because they're intimately familiar with the state perspective.

But other agencies, and here I would hazard to cite the Office of the Comptroller of the Currency as a potential example, are quite the opposite. In the banking world, you have federally chartered banks and state chartered banks. The OCC is in charge of federally chartered banks and states are in charge of state chartered banks, and there's not a lot of interaction between those two groups. So when the OCC seeks to preempt state regulation of state chartered operating subsidiaries of federal banks, they're entrenching on the turf of the state regulators in a big-time way, and they don't really have a lot of information as to what the impacts of that are going to be. So in that context, Congress may in fact be a better forum for sorting out state versus federal interests than the agency is.

So it's a very competent question and one reason I think maybe Herb

Wechsler's analysis is not the way to go in trying to sort out these issues case by case.

**JUDGE O'SCANNLAIN:** Before taking a comment from Professor Sharkey, Professor Merrill, would you like to hazard a guess on what the Supreme Court will do in the OCC bank case? This is *Waters*.

**PROFESSOR MERRILL:** This is my private view and not the view of any client that I represent in this case. My guess is that the Court is going to look at this and they're going to say, is there any way we can decide this without reaching this issue? I think they'll figure out a way of doing that. So this big debate, which has been briefed in the *amicus* briefs between *Chevron* deference, *Skidmore* deference, and no deference on this little issue, my guess is will not be resolved by *Waters*. But I've been wrong before.

**JUDGE O'SCANNLAIN:** Professor Sharkey.

**PROFESSOR SHARKEY:** I just wanted to make a point about the presumption against preemption. In these products liability Supreme Court cases, it's actually interesting to trace where the presumption does and where it does not rear its head. So in *Geier*, of course, there's not a mention in the majority opinion about this alleged presumption against preemption, and the Court in that instance preempts. In the *Bates* case, the presumption comes back in full force. So I think that if anything—at least in these products cases—the Court has applied the presumption against preemption in a haphazard manner.

(Panel concluded.)